

Objection to Claims

Claim 23 is objected to by the Examiner as being improperly dependent upon claim 33. In response, claim 23 is rewritten as new claim 56. The objection should accordingly be withdrawn.

Rejection under 35 USC 112 (paragraph one)

Claims 22-27, 33 and 46-55 stand rejected under 35 USC 112 (paragraph one) as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In essence, the Examiner appears to focus the rejection upon the use of the term “prophylaxis” of IBD. This rejection respectfully is traversed.

With regard to the “prophylaxis” embodiment, xanthan gum and HPMC are both mucoadhesive polymers which are not metabolized by the body. Hence, these compounds pass through the GI tract unchanged. Both polymers are inert (e.g., they are relatively resistant to micro-organisms) and have a high molecular weight. See page 1, lines 11-19 of the specification in this regard. Both xanthan gum and HPMC contact the gut mucosa and act as a protective layer – e.g., a kind of “dressing” for inflamed mucosa which prevents, in the case of pouchitis, for instance, the deleterious effect of the fecal

1-3, 6, 15, 22, 24-27, 33 46-55

23 Canceled
56 add

37-39, 42, 43, 45-56

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stasis of the bile acids and of the micro-organisms which are known to be at the origin of the pouchitis.

Patients with pouchitis (who also have primary sclerosing cholangitis) have a 63% risk of developing chronic pouchitis (Penna C., Dozois, R., Tremaine, W. et al, "Pouchitis after Ileal Pouch-Anal Anastomosis for Ulcerative Colitis Occurs with Increased Frequency in Patients with Associated Primary Sclerosing Cholangitis", *Gut*, 1996, Feb. 38(2),234-239. It would be appropriate to use the enemas of the present invention as a prophylactic in these cases. In addition, patients with recurrent pouchitis who are brought into remission with antibiotics could be treated with a prophylactic therapy such as these enemas. This has recently been shown to be effective therapy using probiotic therapy for prophylaxis of pouchitis. Minura, T., *Gut*, 53: 108-114, 2004.

In view of the above facts, applicants assert that the claimed enemas could be successfully used as prophylactic compositions. One of ordinary skill in the art would readily appreciate and be able to practice the claimed prophylactic method using the recited compositions given available information with the requisite degree of predictability, the fact that the amount of direction provided is minimal, the fact that little if any experimentation is required, and the relatively simple nature of the claimed invention.

In view of the above, it is believed that the rejection is without basis and should be withdrawn.